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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/226,597	01/07/1999	JULIO PIMENTEL	ANIT0018U-US	9844

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EXAMINER	
GABEL, GAILENE	
ART UNIT	PAPER NUMBER
1641	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	09/226,597	PIMENTEL, JULIO	
	Examiner	Art Unit	
	Gailene R. Gabel	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2007 and 14 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 12-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 12-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. Applicant's amendment and response filed August 3, 2007 is acknowledged and has been entered. Claims 24, 27, 28, 30, 31, 33-35, 37, 38, 40, and 41 have been amended. Claims 20 and 21 have been cancelled. Accordingly, claims 1-5, 12-19, and 22-42 are pending. Claims 1-5, 12-19, and 22-42 are under examination.

Rejections Withdrawn

2. All rejections not reiterated herein have been withdrawn.

3. The rejection of claims 1, 2, 16, 18, 19, 26-28, 32, and 33 on the grounds of provisional nonstatutory double patenting over claims 1, 8, 14, 18, 31, 47, and 51 of copending Application No. 08/888,202, is now moot, in light of Applicant's abandonment of the application on September 7, 2007. This rejection remains moot, but subject to reinstatement in the event that ASN 08/888,202 is petitioned for revival pursuant to further prosecution of the application.

4. In light of Applicant's arguments, the rejection of claims 1-5, 12-19, and 22-42 under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US Patent 5,919,451) in view of LeClercq et al. (Metabolism of very low density lipoproteins in genetically lean or fat lines of chicken, Reproduction, Nutrition, Development, 30 (6): 701-715 (1990)), is hereby, withdrawn.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 3, 12, 34, and 35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is ambiguous because it is unclear how after feeding the animal the liposome-encapsulated anti-lipase antibody in claim 1 from which the instant claim ultimately depends, it can further [comprising] be stored in a wet state then further freeze-dried for storage. Does Applicant perhaps intend, "wherein the liposome-encapsulated anti-lipase antibody is in a wet state and then freeze-dried for storage, prior to feeding.

Claim 12 is vague and indefinite because the term, "forming" appears to be a mental step, which does not appear to encompass an active method step that requires preparing or making the component. Specifically, liposomes and anti-lipase antibodies can be caused to form liposome-encapsulated anti-lipase antibodies, such as by mixing or combining the components. Does Applicant intend that the individual components are combined so as to form the liposome-encapsulated anti-lipase antibodies.

Claim 34 is ambiguous because it is unclear how after feeding the animal the liposome-encapsulated anti-lipase antibody in claim 32 from which the instant claim

ultimately depends, it can further [comprising] be stored in a wet state then further freeze-dried for storage. Does Applicant perhaps intend, "wherein the liposome-encapsulated anti-lipase antibody is in a wet state and then freeze-dried for storage, prior to feeding.

Claim 35 is indefinite because it is unclear how the instant active method step of "mixing the liposome-encapsulated anti-lipase antibody with food" can be performed after feeding it to the animal, as recited in claim 32 from which it depends. Does Applicant perhaps intend, "wherein the liposome-encapsulated anti-lipase antibody is mixed with food/feed, prior to feeding.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. For purposes of prior art rejection, the claims, as written, are interpreted as follows. Note that unpatented claims are given the broadest reasonable interpretation consistent with the specification.

A. Claims 1-5, 12-15, 32-35, and 42 are method of use claims as follows:

Claims 1-5 and 12-15 are drawn to a method: feeding an animal food and liposome-encapsulated anti-lipase antibodies.

Claims 32-35 and 42 are drawn to a method: feeding an animal liposome-encapsulated anti-lipase antibodies.

B. Claims 16-24, 26-28, and 39-41 are product/composition claims as follows:

Claims 16-24 are drawn to a composition: mixture of food an liposome-encapsulated anti-lipase antibodies.

Claims 26-28 are drawn to a composition: liposome-encapsulated anti-lipase antibodies.

Claims 39-41 are drawn to a composition: liposomes and anti-lipase antibodies in a solution.

C. Claims 25, 29-31, and 36-38 are method of making claims as follows:

Claim 25 is drawn to a method of making a composition: mixture of food and liposome-encapsulated anti-lipase antibodies.

Claims 29-31 are drawn to method of making a composition: liposome-encapsulated anti-lipase antibodies.

Claims 36-38 are drawn to making a composition: a solution containing liposomes and anti-lipase antibodies.

From here on, liposome-encapsulated anti-lipase antibodies are LE anti-lipase Abs.

7. Claims 1-5, 12-19, and 22-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cook et al. (US Patent 5,725,873, filing date July 22, 1996) in view of Ohkaru et al. (Application of two monoclonal antibodies to either an immunosorbent enzyme assay or a competitive binding enzyme immunoassay for human serum pancreatic lipase, Clin. Chim. Acta, 182 (3): 295-300 (1989), Abstract Only).

Cook et al. disclose a method of feeding to an animal a food composition comprising a liposome-encapsulated antibody (Abstract). The antibody may be provided in solution in a wet state, in an aqueous or lipid carrier, i.e. liposome-encapsulation, and may also be directly applied to the pellet core without a carrier (freeze-dried) such as a powder (column 1, lines 32-43 and Example 2). The antibody is encapsulated in liposomes having an inner core comprising non-fat nutrients and an outer layer of fat which contains effective amount of antibodies (see column 1, lines 52-65; column 2, lines 22-46).) The antibody is avian, i.e. obtained from egg of a hen which has been injected with antigen that results to the production of its corresponding antibodies (column 1, lines 34-39 and column 2, lines 6-9). The food composition is made by forming a nutrient mixture and then depositing the liposome-encapsulated antibody into the pellet core (column 1, line 66 to column 2, lines 1-5 and 10-23). The food content comprises protein and carbohydrate may also include vitamins and dietary lipid (column 2, lines 27-34 and 51-67). The food composition and method are prepared as animal feed for use in either mammals (pets), or avians such as ducks, chickens,

and turkeys (see Example 3; Table 1; and column 4, lines 34-37). The food composition containing the avian antibody is fed to the animal in an amount that may be effective in passively immunizing the animal or otherwise enhancing the efficiency of feed conversion by the animal (column 2, lines 35-38). The antibodies may be any one which can which can alter physiological processes that adversely affect growth and efficiency. The antibodies can be those that are against diseases or specific for endogenous antigens present in the digestive system that regulate food intake and gastrointestinal motility (column 2, lines 39-47).

Cook et al. differ from the claimed invention in failing to teach that the antibody is anti-lipase antibody directed against pancreatic lipase antigen.

Ohkaru et al. teach raising two monoclonal antibodies against pancreatic (gut) triacylglycerol lipase. One of the monoclonal antibodies specifically inhibited the lipase antigen (Abstract).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to encapsulate the anti-lipase monoclonal antibody raised by Ohkaru against pancreatic lipase antigen that specifically inhibited the pancreatic lipase antigen, into the liposomes taught in the method of Cook, because Cook taught that any antibody that is specific for gastrointestinal antigen intended for oral administration or feeding with food so as to be protected from enzyme degradation, can be encapsulated so as to protect the antibodies intended to bind a specific enzyme.

Cook et al. and Ohkaru et al. do not disclose that the composition contains 25 to 1000 mg of liposome encapsulated anti-lipase antibodies per kilogram of the animal food, as recited in claims 14, 15, 17, and 23.

Cook et al. specifically disclose administering safe and effective amounts of antibody that would help protect the animal from disease or other antigens that can adversely affect animal's growth or the efficiency of the animal to convert feed into desirable body tissue. Therefore, the amount of liposome-encapsulated anti-lipase antibody contained in a food composition should be a safe and effective quantity.

Such ranges of antibody concentrations in food composition, are rendered as result effective variables, which the prior art references have shown may be altered in order to achieve optimum results. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233,235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215,218-219 (C.C.P.A. 1980). Since Applicant has not disclosed that the specific limitations recited in claims 14, 15, 17, and 23 are for any particular purpose or solve any stated problem and the prior art teaches that effective concentrations of antibodies or compounds used

may vary according to the animals being fed and/or their characteristics, absent unexpected results, it would have been obvious for one of ordinary skill to discover the safe and effective amounts of antibodies and compounds used for the composition and method disclosed by the prior art by normal optimization procedures.

Response to Arguments

8. Applicant's arguments with respect to claims 1-5, 12-19, and 22-42 based on the combination of Cook et al. (US Patent 5,919,451) with LeClercq et al. have been considered but are moot in view of the new grounds of rejection.

9. Applicant's arguments filed August 3, 2007 have been fully considered but they are not persuasive.

A) Applicant's arguments in regards to US Patent 5,919,451 Cook et al. reference as not being prior art, have been considered but are not persuasive, upon further reconsideration of US Patent 5,919,451 and substantive review of US Patent 5,725,873. Specifically, the subject matter discussed in US Patent 5,725,873 substantially teaches compositions, methods of making liposome encapsulated antibodies, and methods of using liposome encapsulated antibodies for incorporation with food for purposes of oral administration to animals, the subject matter applied of which is consonant to that described and relied upon in US Patent 5,919,451, and now relied upon in a 103 rejection for this Office Action.

B) Applicant argues that Cook does not disclose feeding anti-lipase antibodies; the only actual antibody disclosed in Cook is antibody to Cholecystokinin (CCK) and that the only antigen disclosed in Cook is CCK and that all of Cook's examples show feeding antibody to CCK to reduce weight gain. Applicant specifically contends that the goal and effect of the instant application is to feed LE anti-lipase Abs in order to decrease feed conversion efficiency and reduce weight gain, and increase weight loss, which is contradictory to Cooks goal and effect which is to inhibit physiological processes that adversely affect growth and efficiency, with results shown to be "increased feed conversion efficiency and weight gain".

In response to applicant's arguments against the Cook et al. individually as a reference failing to show feeding LE anti-lipase Abs, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, the rejection is based on the combined teaching of Cook et al. with Ohkaru et al. to render the claimed invention obvious. As recited, the claims simply recite claims drawn to compositions for feeding, drawn to method of making compositions for feeding, and drawn to method of using the compositions for feeding [previously formed] composition or food mixture comprising LE anti-lipase antibodies to animals. As such, Cook et al. is relied upon for teaching encapsulation of avian antibodies to gut antigens for incorporation into feed for intake. Ohkaru et al. is relied upon for combination with Cook et al. for teaching generation of pancreatic anti-lipase antibody from pancreatic lipase antigen that is able

to specifically inhibit the lipase antigen that is present in the gut. It would have been obvious to one of ordinary skill in the art at the time of the instant invention to encapsulate the anti-lipase monoclonal antibody raised by Ohkaru against pancreatic lipase antigen that specifically inhibited the pancreatic lipase antigen, into the liposomes taught in the method of Cook, because Cook taught that any antibody that is specific for gastrointestinal antigen intended for oral administration or feeding with food so as to be protected from enzyme degradation, can be encapsulated so as to protect the antibodies intended to bind a specific enzyme.

In response to applicant's argument that the Cook reference fails to show certain features of applicant's invention (i.e., feeding LE anti-lipase Abs with the goal to decrease conversion efficiency, reduce weight gain, and increase weight loss) which encompass the goal and effect intended in Applicant's disclosure, it is noted that such features upon which applicant rely are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Applicant's arguments are therefore not persuasive because the arguments are not commensurate in scope with the claimed invention. Specifically, Applicant's claimed invention as recited in claims 1-5, 12-19, and 22-42 only seek enablement in making compositions comprising liposome-encapsulated anti-lipase antibodies for incorporation into animal feed for purposes of feeding, i.e. oral administration, of the composition to the animal, without any regard as to the functionality of the antibody after administration.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R. Gabel whose telephone number is (571) 272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gailene R. Gabel
Primary Examiner
Art Unit 1641

October 16, 2007